REMARKS

Status of the Claims

Prior to the amendments set forth herein, Claims 75, 76, 78, 80, 82, 83, 87-106, and 108-111 were pending and stand rejected. As set forth above, independent Claims 75, 78 and 82 have been amended to direct the pending claims in the application to methods of inhibiting Raf kinase activity in a human or animal subject suffering from a Ras/mitogen-activated protein kinase signal pathway-mediated cancer disorder. In addition, Claims 75 and 92-94 have been amended to correct clerical errors. Support for new Claim 112 is found in the specification at page 31, line 22, through page 32, line 2. It is believed that Claims 75, 76, 78, 80, 82, 83, 87-106, and 108-112 are in condition for allowance in view of the foregoing amendments and following discussion. Reconsideration and favorable action are requested.

Telephone Interview

The telephone interview of May 19, 2008, between applicants' representative Verne A. Luckow, Ph.D., Examiner Shobha Kantamneni, and Supervisory Examiner Sreeni Padmanabhan is hereby acknowledged. During the interview, enablement of Claims 75, 76, 78, 80, 82, 83, 87-106, and 108-111 under 35 U.S.C. § 112 in view of the disclosure in the application, the art of record relating to the use of Raf kinase inhibitors in the treatment of Raf kinase mediated disorders, the existence of multiple clinical trials concerning Raf kinase inhibitors, such as BAY-43-9006, GW-5054, L-779450, and geldamycin, for the treatment of specific cancers, and the role shown in the art of inhibitors of Raf kinase in the treatment of various disorders was discussed. No agreement was reached. However, the Examiner agreed to consider claim amendments directed to methods of inhibiting Raf kinase activity in a human or animal subject suffering from a Ras/mitogen-activated protein kinase signal pathway-mediated cancer disorder. Such amendments are presented herein.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

Rejections under 35 U.S.C. § 112, first paragraph, enablement

Claims 75, 76, 78, 80, and 108 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Claims 82, 83, 87-106, and 109-111 also stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner's has characterized the invention as being complex in that it encompasses the treatment of any type of cancers as in Claim 75, and types of cancer as in Claims 78 and 82 mediated by Ras/mitogen activated protein kinase pathway. As stated by the Examiner, "While the state of the art is relatively high with regard to treating specific cancers in general, and specific cancers mediated by Ras/mitogen-activated protein kinase signal pathway, the state of the art with regard to treating any cancer disorder is underdeveloped. In particular, there is no known anticancer agent which is effective against all cancers." Further, the Examiner has indicated that the applicant has not provided any competent evidence that the instantly disclosed tests are highly predictive for any or all types of cancers disclosed and embraced by the claim language for the intended host. Lack of a working example is a critical and crucial factor to be considered, especially in a case involving an unpredictable and undeveloped art.

In order to facilitate prosecution of the present application, and without acquiescence in the Examiner's rejections or prejudice to applicants' right to pursue claims directed to the treatment of Ras/mitogen-activated protein kinase signal pathway-mediated cancer disorders in one or more separate applications, Claims 75, 78 and 82 have been amended to be directed to inhibiting Raf kinase activity in a human or animal subject suffering from a Ras/mitogen-activated protein kinase signal pathway-mediated cancer disorder. As previously discussed in depth, it is clear that the compounds of the claims have been demonstrated to be effective in the inhibition of Raf kinase activity, and the record is now replete with citations to credible published journal reports establishing the role of Raf kinase and Ras/mitogen-activated protein

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

kinase signal pathway in specific cancer disorders. Accordingly, it is respectfully submitted that the Examiner's rejections of Claims 75, 76, 78, 80, 82, 83, 87-106, and 108-111 should properly be withdrawn.

New Claim

New Claim 112 is dependent on existing Claim 82 and further specifies that the hematological cancer disorder is chronic myelogenous leukemia. No new matter has been added.

CONCLUSION

In view of the foregoing amendments and comments, it is believed that Claims 75, 76, 78, 80, 82, 83, 87-106, and 108-112 are in condition for allowance. Entry of the foregoing amendments and favorable action are requested. Please contact applicants' representative at the number set forth below to discuss any issues that will facilitate the prosecution of this application.

Respectfully submitted,

CHRISTENSEN O'CONNOR
JOHNSON KINDNESS[PLLC]

Dennis K. Shelton
Registration No. 26,997
Direct Dial No. 206.695.1718

DKS

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS[PLLC]
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100